K094050 #1/5

5.0 510(k) SUMMARY

SEP 1 3 2010

This 510(k) Summary for the ConforMIS iTotal® Cruciate Retaining (CR) Knee Replacement System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name and Address:	ConforMIS Inc. 2 Fourth Ave. Burlington, MA 01804
Contact Person:	Amita S. Shah, Director, Quality Assurance and Regulatory Affairs
Date:	December 29, 2009
Name of Medical Device:	Device Regulation: 21 CFR 888.3560 Product Code: OR (87) JWH, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Common/Usual Name: Cruciate Retaining Total Knee Replacement System Proprietary Name: ConforMIS iTotal Cruciate Retaining Knee Replacement System
Device Classification:	Class II
Indications for Use:	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The Indications for Use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants. The iTotal® CR Knee Replacement System is intended for cemented use only.

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510(k) SUMMARY

Device Description:

The proposed iTotal CR Knee Replacement System (hereafter referred to as the "iTotal CR KRS") is a patient specific tri-compartmental faceted posterior cruciate ligament (PCL) retaining knee replacement system. The iTotal CR KRS is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component. The product design incorporates a bone preserving approach with minimal bone resection of the tibia and femur for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma.

Using patient imaging (either CT or MR scans), a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The device is manufactured from cobalt chromium molybdenum ("CoCrMo") alloy. The tibial component includes a metal tray manufactured from CoCrMo alloy and either one or two polyethylene inserts manufactured from UHMWPE of identical configuration. The patellar component is manufactured from UHMWPE.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent to the ConforMIS Tri-Compartmental Resurfacing (tCR) device (K052687), the Stryker Triathlon CR Total Knee System (K040267) and the Smith & Nephew Journey Bicruciate Stabilized Knee System (K042515) all of which are cemented total knee replacement systems. See Table 5-1 below for a more detailed comparison.

Table 5-1: Comparison of the Proposed iTotal CR KRS and Predicate Knee Systems

Feature	Proposed Device iTotal CR Knee Replacement System	Predicate Device ConforMIS Tri-Compartmental Resurfacing (tCR) device (K052687)	Predicate Device Stryker Triathlon CR Total Knee System (K040267)	Predicate Device Journey Bicruciate Stabilized Knee System (K042515)
Indications for Use	The iTotal® CR Knee Replacement System is intended for use as a total	The ConforMIS Inc., Tri-Compartmental	The Triathlon CR Total Knee System consists of femoral component, tibial	Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis,

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	knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bi-compartmental prosthesis. The indications for use include: • Painful joint disease due to osteoarthritis, traumatic arthritis or rheumatoid arthritis or osteonecrosis of the knee • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability • Failed osteotomies, hemiarthoplasties, unicondylar, patellofemoral or bicompartmental implants. The iTotal® CR Knee Replacement System is intended for cemented use only.	Resurfacing (tCR) Device is intended for use in patients with severe knee joint pain and disability. The indication for use include: • Painful joint disease due to osteoarthritis , traumatic arthritis or rheumatoid arthritis of the knee • Post traumatic loss of joint function • Valgus or varus deformity of the knee The ConforMIS Tri-compartmental Resurfacing (tCR) device is intended for use only with bone cement.	insert, and all polyethylene patellar components that are intended to be used with previously cleared Triathlon Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon All Polyethylene Patellar components are intended to be used with femoral components of the previously released Duracon Total Knee System, as well as the previously released Triathlon PS femoral component in situations where replacement of the articular surface of the patella is required. The Triathlon CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indication and contraindications are listed below Indications: • Painful, disabling joint disease of the knee resulting from: non inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis • Post- traumatic loss of knee joint configuration and function • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Revision of previous unsuccessful knee replacement or other procedure • Fracture of the distal	osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result: failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate are absent or incompetent and collateral ligaments remain intact. Smith & Nephew, Inc., High Performance Knee components are indicated for use only with cement and are single use devices.

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			femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.	
Intended for Cement use only	Yes	Yes	Yes	Yes

Components	• Femoral Component
	• Tibial Implant
	  • Metal backed tibial component
	• Patellar component
		• Femoral Component
		• Tibial Implant
		  • All Poly tibial compon ent
		• Patellar component
			• Femoral Component
			• Tibial Implant
			  • Metal backed tibial component
			• Patellar component
				• Femoral Component
				• Tibial Implant
				  • Metal backed tibial component
				• Patellar component

Materials	• Femoral Implant- CoCrMo
	• Metal-Backed Tibial Components:
	  • Tibial tray- CoCrMo
	  • Tibial Inserts- UHMWPE
	• All Polymer Patellar Component- (UHMWPE)
		• Femoral Implant- CoCrMo
		• All poly tibia component -UHMWPE
		• All Polymer Patellar Component- (UHMWPE
			• Femoral Implant- CoCrMo
			• Metal-Backed Tibial Components:
			  • Tibial tray*- CoCrMo
			  • Tibial Insert- UHMWPE with CoCrMo locking wire
			• All Polymer Patellar Component- (UHMWPE)
				• Femoral Implant- Oxidized Zirconium
				• Metal-Backed Tibial Components:
				  • Tibial tray- CoCrMo
				  • Tibial Insert-UHMWPE
				• All Polymer Patellar Component-(UHMWPE)

Design	Knee joint patellofemorotibial semi – constrained cemented prosthesis	Same	Same	Same
Principle of Operation	Cemented Use fixed Bearing Design	Same	Same	Same
Patient-Specific	Yes	Yes	No	No
Patellar Design/Dimensions	Symmetrical, offered in sizes ranging from 32, 35, 38 and 41 mm, with corresponding heights of 6, 7, 8.5 and 10 mm	Offset Dome	Symmetrical or Asymmetrical, offered in sizes ranging from 27 to 39 mm in diameter and 8 to 11 mm in thickness.	Symmetrical, offered in sizes ranging from 26 to 41mm in diameter and 7 to 9 mm in thickness
Minimum Thickness of Tibial Insert (UHMWPE)	6 mm	All poly tibial component -6mm	6mm	6mm
Posterior Cruciate Ligament (PCL) Sparing	Yes	Yes	Yes	No Posterior stabilized

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Safety and Performance:

The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate devices for the proposed intended use.

The following testing was performed on the subject device: Femoral Fatigue Testing, Kinematic Range of Motion Testing, Stability Characteristics Testing, Patello-Femoral Lateral Stability Testing, Contact Area and Surface Stress for the Patello-Femoral Articulation testing, Tibial-Femoral Contact Areas and Stress Testing, Modular Assembly and Disassembly Characteristics of the iTotal Tibial Plateau Testing and UHMWPE Characterization. Clinical data is not necessary to demonstrate substantial equivalence. Results of the bench testing conducted demonstrate that the iTotal KRS is substantially equivalent to the Predicate Knee Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConforMIS, Inc.
% Ms. Amita S. Shah
2 Fourth Avenue
Burlington, Massachusetts 01803

SEP 1 3 2010

Re: K094050
Trade/Device Name: ConforMIS iTotal® Cruciate Retaining (CR) Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: July 16, 2010
Received: July 19, 2010

Dear Ms. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATION FOR USE STATEMENT

SEP 1 6 2010

510(k) Number (if known): K094050

Device Name: ConforMIS iTotal® Cruciate Retaining (CR) Knee Replacement System

Indications for Use:

The iTotal® CR Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The Indications for Use include: '

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The iTotal CR KRS is intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094050